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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,348	08/15/2003	Keith K. Daellenbach	BJT 332B	1593
23581	7590	06/28/2006	EXAMINER	
KOLISCH HARTWELL, P.C. 200 PACIFIC BUILDING 520 SW YAMHILL STREET PORTLAND, OR 97204			SCHELL, LAURA C	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/642,348

Applicant(s)

DAELLENBACH, KEITH

Examiner

Laura C. Schell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13-21, 23, 24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21, 23, 24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-11, 14-18, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (US Patent No. 6,709,427). Nash discloses a needle free jet injection device (Fig. 7) for delivering a fluid into an internal organ, the device comprising: a rigid end effector (204; col. 23, lines 13-16) including at least one injection orifice disposed on a sidewall of the end effector (212), the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (col. 23, lines 13-16); the end effector capable of being positioned within the prostate gland, wherein the at least one injection orifice is oriented generally laterally to the longitudinal axis of the end effector (Fig. 7); a fluid reservoir (72) in fluid communication with the end effector; and an ejection mechanism (214) adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice with sufficient pressure to penetrate a tissue while preserving the functionality of the tissue (col. 24, lines 18-24).

Nash further discloses that the end effector includes a plurality of injection orifices located at the distal end, and that the orifices can be arranged linearly, in rows or offset from each other (col. 23, lines 58-62). Nash also discloses that the end effector includes a straight shaft section (200) and a distal section (near 212). Nash further discloses that the ejection mechanism is adapted to allow the device to eject multiple doses (col. 24, lines 29-31). Nash also discloses that the end effector can have a blunt distal end (Fig. 8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (US Patent No. 6,709,427) in view of Glines et al. (US Patent No. 6,716,190). Nash discloses the device substantially as claimed except for the fluid of injection being ethanol. Glines, however, discloses a needle-free jet injection device which delivers ethanol (col. 18, lines 29-32). Therefore it would have been obvious to one of ordinary skill in the art to have used the needle-free jet injection device of Nash to deliver ethanol, as taught by Glines, because ethanol is fluid that is particularly useful to inject into tissues, particularly to ablate a tissue at the site of the jet injector.

Claims 19, 20 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Kollias et al. (US Patent No. 6,251,099). Nash

discloses the invention substantially as claimed including an injection mechanism in which the injection pressure can be adjusted and selected, however it does not disclose expressly a mechanism configured to provide a rise time to a peak pressure wherein the rise time and peak pressure selection are to preserve tissue functionality. Kollias, however, discloses a needle-less injection device in which the peak injection pressures and rise time to these pressures can be selected in order to preserve the functionality of the tissue (col. 1, lines 55-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Nash with the rise time and peak pressure selections of Kollias, in order to provide a safe and customizable medical device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-11, 13-21, 23 and 24 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's arguments that the prior reference (Micro-Heart) was not rigid, the new reference (Nash) discloses that it is rigid, not a catheter, and meant to be used during open heart surgery, such that it is not mean to be snaked through the vasculature, as further emphasis of its rigidity, as cited above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*